TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 2001-0878.ORI

In Re Application Of: **Alexander James Wigmore**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/831,681	May 10, 2001	S.T. Tran	022476	1615	7056

Title:

TREATMENT OF ALLERGIC CONDITIONS

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

a Reply Brief in response to Examiner's Answer dated April 13, 2006

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Dated: **April 18, 2006**

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PATENT APPLICATION

ATTORNEY DOCKET NO. 2001-0878.ORI

UNITED STATES PATENT AND TRADEMARK OFFICE

Date	:	April 18, 2006
Re App	:	Alexander James Wigmore
Serial No.	:	09/831,681
Filed	:	May 10, 2001
Title	:	TREATMENT FOR ALLERGIC CONDITIONS
Art Unit	:	1615
Examining Attorney	:	Susan T. Tran

REPLY BRIEF

Attn: Board of Appeals and Interferences

Appellant's Reply Brief (37 C.F.R. §41.41)

This Reply Brief is submitted in response to the Examiner's Answer of April 13, 2006 to Applicant's Appeal Brief filed on January 20, 2006.

This Brief contains the following items as set forth below (37 C.F.R. §41.37(c)):

A. Status of Claims
B. Grounds of Rejection to be Reviewed on Appeal
C. Argument

A. Status of Claims (37 C.F.R. §41.37(c)(1)(iii)):

The claims in the application are 1-36. Of these claims:

Claims 10-15 and 17-29 are withdrawn from further consideration;

Claims 6, 31, and 32 are cancelled

Claims 1-5, 7-9, 16, 30, and 33-36 are pending;

Claims 1-5, 7-9, 16, 30, and 33-36 stand rejected.

The claims on appeal are 1-5, 7-9, 16, 30, and 33-36.

B. **Grounds of Rejection to be Reviewed on Appeal (37 C.F.R. §41.37(c)(1)(vi)):**

Whether Claims 1-5, 7-9, 16, 30, and 33-36 are unpatentable under 35 U.S.C. §103(a) over Watts et al. (U.S. 6,200,602).

C. **Argument (37 C.F.R. §41.37(c)(1)(vii)):**

Watts et al. (U.S. 6,200,602) Fail to Establish a Prima Facie Case of Obviousness Under 35 U.S.C. §103(a).

The claims currently on appeal recite an oral drug delivery composition having a chromone and a disintegrant material in a minimum concentration ratio by weight of at least 1.2:1 of disintegrant material to chromone. The recited concentration ratios of disintegrant to chromone enables the claimed rapid chromone dissolution upon exposure to simulated intestinal fluid (see page 17, lines 10-23 of the PCT Application Publication No. WO 00/27392 ("the Application")).

The Watts et al. '602 patent, however, not only fails to disclose the claimed disintegrant to chromone concentration ratios, but also fails to suggest any link between the relative disintegrant concentration and rapid chromone dissolution in simulated intestinal fluid. "In determining whether a case of prima facie obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification", In re Lalu, 747 F.2d 703, 705 (Fed. Cir. 1984). Here, while Watts et al. '602 mention the possible use of known pharmaceutical excipients, no

teaching is made of the concentrations of such excipient materials in the compositions of Watts et al. '602. Moreover, Alexander Wigmore specifically declared in Applicant's Response of May 29, 2003 ("Exhibit A" in Appeal Brief) that the claimed disintegrant to chromone concentration ratio "is far in excess of the quantity of disintegrant conventionally used". Accordingly, one of ordinary skill in the art, without express teaching to the contrary, would conventionally employ a substantially lower concentration of disintegrant in the compositions of Watts et al. '602, as compared to the disintegrant concentration ratios now claimed. Since Watts et al. '602 provide no guidance in modifying the disintegrant concentrations from that conventionally known in the art, it is not now proper to allege that Watts et al. '602 may in fact disclose the disintegrant concentrations now recited in the claims under appeal. Under the rule stated by In re Lalu, 747 F.2d at 705, a case of prima facie obviousness therefore does not exist.

At pages 3-4 of the April 13, 2006 Answer, the Examiner impliedly asserts that the claimed and prior art products are identical or substantially identical in structure or composition, such that the composition of Watts et al. '602 would have similar dissolve rates to that

now claimed. Applicant strenuously disagrees with the Examiner's assertion, in that nowhere do Watts et al. '602 teach or suggest the concentration ratios of disintegrant to chromone. Moreover, in view of the Declaration of Alexander Wigmore identified above, one of ordinary skill in the art would in fact utilize a substantially lower concentration ratio of disintegrant than that utilized in the presently claimed compositions. Such compositions having a substantially lower concentration ratio of disintegrant material would fail to exhibit the rapid dissolve rates unexpectedly achieved in the present invention (see page 3, lines 12-27 of the Application).

Additionally, Watts et al. '602 specifically teach away from the release of the drug in the small intestine (column 6, lines 21-60), as asserted by the Examiner on pages 3-4 of the Answer. As such, Watts et al. '602 do not teach a composition that ensures release of the drug in the small intestine. The presently claimed compositions, by contrast, do indeed enable rapid chromone dissolution in the small intestine. Specifically, the pending claims recite a substantial portion of chromone dissolution within ten (10) minutes or less of exposure to simulated intestinal fluid. Such claim elements are an in vitro explanation that reflects the in vivo environment, that one

of ordinary skill in the art would readily understand that the claimed compositions would similarly provide for chromone dissolution in vivo within the small intestine (see pages 56-57 of the Application). Moreover, it is well known in the art that substances take significantly longer than ten (10) minutes to pass through the small intestine, and usually more than two hours. As such, the claim recitation of chromone dissolution within ten (10) minutes or less of exposure to simulated intestinal fluid is indeed commensurate with the statement that such compositions provide for rapid chromone dissolution in the small intestine.

It is well established that the failure of the cited prior art to teach or suggest a recited claim element prevents the formation of a prima facie case of obviousness. (In re Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993)). As described above, Watts et al. '602 fail to teach or suggest the claimed disintegrant concentration ratios. A fact pattern similar to that at issue here arose in Upjohn Company v. Mova Pharmaceutical Corp., 225 F.3d 1306 (Fed. Cir. 2000), wherein a claim recited a pharmaceutical composition containing at least 70% by weight of spray-dried lactose as the preponderant excipient, while the prior art references showed the use of

spray-dried lactose but not in the claimed percentage with the claimed type of drug (Upjohn Company, 225 F.3d at 1312). The Court in Upjohn Company found "no evidence of any teaching or suggestion in the prior art to use at least about 70% of spray-dried lactose" in the pharmaceutical formulation (Upjohn Company, 225 F.3d at 1312). Here, the Watts et al. '602 patent indicates the use of disintegrant material, but fails to provide any teaching or suggestion to use such disintegrant material in a concentration ratio of at least 1.2:1 of the disintegrant to chromone, as is presently claimed. By the standard stated in Upjohn Company, therefore, Watts et al. '602 may not be properly construed to teach or suggest the presently claimed disintegrant to chromone concentration ratios. Without such teaching, no prima facie case of obviousness against the claims presently under appeal may be based solely upon Watts et al. '602.

Since no Prima Facie Case of Obviousness is Properly Established by Watts et al. '602, Applicant Bears no Burden to Compare the Claimed Composition to Those of Watts et al. '602.

The Examiner indicates at pages 5-6 of the Answer that insufficient evidence has been provided by the Applicant to overcome the claim rejections under 35 U.S.C. §103 by Watts et al. '602, since no side-by-side comparison between the

compositions of the claimed invention and those of Watts et al. '602 have been provided for the record. However, it has been clearly defined that only when a prima facie case of obviousness has been established by the Patent Office does the burden shift to the Applicant to move forward (In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984)). Here, and as described above, no such prima facie case of obviousness has been established by the Examiner in relying upon Watts et al. '602. Accordingly, Applicant does not bear the burden of providing rebuttal evidence, such as in the form of a side-by-side comparison between the compositions of the claimed invention and those of Watts et al. '602.

Moreover, it has been the consistent position of the Applicant that such a side-by-side comparison is infeasible given the lack of disclosure provided in Watts et al. '602. As stated above, Watts et al. '602 provide no guidance whatsoever on the amount of disintegrant material to use in relation to sodium cromoglycate, the sole chromone referred to by Watts et al. '602 as "polar drugs". No teaching is found in Watts et al. '602 of amounts of such sodium cromoglycate that should be used in the compositions thereof. Accordingly, no basis is provided in Watts et al. '602 to create a composition containing both a chromone and

a disintegrant in order to conduct the side-by-side comparisons called for by the Examiner.

The Examiner notes at page 5 of the Answer that Watts et al. '602 teach the desirability to increase drug absorption to the colon (see column 8, lines 26-60). While the Watts et al. '602 patent is directed toward the assessment of systemic effects arising from the administered active agent, the presently claimed compositions are focused on improving dissolution of chromones within the intestinal fluid tract. As such, it is in fact undesired in the compositions of the present invention to facilitate absorption of the drug, as is sought after in Watts et al. '602. In particular, chromones useful in the claimed compositions can cause serious deleterious effects to the patient if it was caused to be absorbed by the body. Accordingly, the passage of Watts et al. '602 identified by the Examiner actually emphasizes the stark differences between the claimed compositions and those described in Watts et al. '602.

It is apparent, therefore, from the foregoing that the Examiner has failed to properly establish the current claim rejections under 35 U.S.C. §103 based upon Watts et al. '602. Applicant therefore respectfully requests this Board

to overturn the claim rejections applied by the Examiner, and to allow the claims as currently pending.

Respectfully submitted,

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